IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, and JANSSEN RESEARCH & DEVELOPMENT, LLC, Plaintiffs, v. MYLAN LABORATORIES LIMITED, Defendant.	Civil Action No. 3:20-cv-13103 (GC) (LHG) (consolidated)

JOINT PRETRIAL SUBMISSION REGARDING LEGAL STANDARDS

Pursuant to the Court's directive at the September 8, 2022 Final Pretrial Conference, the parties hereby jointly submit this statement regarding (1) the asserted independent and dependent representative claims, (2) the definition of a person of ordinary skill in the art, and (3) the legal issues to be decided (with an identification of the key cases on each issue).

1. THE ASSERTED INDEPENDENT AND DEPENDENT REPRESENTATIVE CLAIMS

U.S. Patent 10,143,693 is being asserted in this case. For ease of reference, it may be referred to as "the '693 Patent."

The '693 Patent has 29 claims. Nine of those claims are being asserted in this case. Claims 5-7 and 9-14 are the "Asserted Claims."

Claim 5 is the only independent Asserted Claim. The remaining Asserted Claims—claims 6, 7 and 9-14—are dependent claims, meaning that they each "contain a reference to a claim previously set forth" and then "specify a further limitation of the subject matter claimed." 35 U.S.C. § 112(d). "A claim in dependent form shall be construed to incorporate by reference

all the limitations of the claims to which it refers." *Id.* Each of the asserted dependent claims depends directly or indirectly from claim 5.

For purposes of trial in this action, in order to conserve judicial and party resources, the parties have agreed to present evidence at trial on five representative claims. Claims 5, 6, 7, 10, 11, and 14 are the "Representative Claims." As set forth in the Pretrial Order, three of the Asserted Claims represent other Asserted Claims, as follows:

Representative Claim	Represented Claim
5	
6	
7	
10	9
11	12
14	13

That means that the Court's determination of infringement and validity with respect to claim 10, will apply equally to claim 9. The Court's determination of infringement and validity with respect to claim 11, will apply equally to claim 12. The Court's determination of infringement and validity with respect to claim 14, will apply equally to claim 13. Claims 5, 6 and 7 do not represent any other claim.

A. Infringement Decisions

Janssen bears the burden of proving infringement by a preponderance of the evidence.

Infringement must be considered for each Representative Claim separately. For any Representative Claim that the Court finds that Mylan infringes directly or indirectly (*i.e.*, by inducing infringement), a finding of infringement should be entered for that Representative Claim and its corresponding Represented Claim, if there is one.

Because Claim 5 is independent, if the Court concludes that Mylan does not infringe claim 5, directly or indirectly (*i.e.*, by inducing infringement), then a finding of non-infringement should be entered for all Asserted Claims.

B. Validity Decisions

Mylan bears the burden of proving invalidity by clear and convincing evidence.

Validity must be considered for each Representative Claim separately. If Mylan proves that Asserted Claims 5, 6 and/or 7 are invalid, then a finding of invalidity should be entered for that Asserted Claim. If Mylan proves that Representative Claim 10 is invalid, that finding will apply equally to claim 9. If Mylan proves that Representative Claim 11 is invalid, that finding will apply equally to claim 12. If Mylan proves that Representative Claim 14 is invalid, that finding will apply equally to claim 13.

2. PERSON OF ORDINARY SKILL IN THE ART (POSA)

Obviousness is judged from the perspective of a person of ordinary skill in the art ("POSA"), before the effective filing date of the invention. Written description, enablement, and indefiniteness are judged from the perspective of a POSA as of the effective filing date of the invention.[1]

The parties have agreed that the Court can adopt the following definition of the skill level of a person of ordinary skill in the art ("POSA"):

A POSA would have a Ph.D., Pharm.D., M.D., or equivalent work experience in pharmaceutical sciences, pharmaceutics, pharmacology, pharmacometrics, or medicine or a related field and be capable of working in a team comprising others in the field or related fields.

[1] The parties contend the effective filing date is either April 7, 2015 or May 15, 2015. The parties agree, however, that the Court need not decide whether the effective filing date is April 7, 2015 or May 15, 2015, because the difference will not affect the validity outcome in this case.

At least one person in the team should have experience treating, or collaborating in the treatment of, patients with psychosis, schizophrenia, or bipolar disorder.[2]

3. LEGAL ISSUES TO BE DECIDED

A. Infringement (35 U.S.C. § 271(e)(2)(A) and 35 U.S.C. § 271(b))

In this Hatch-Waxman litigation, Janssen asserts that the submission of Mylan's ANDA is an act of infringement under 35 U.S.C. § 271(e)(2)(A) and that, if its ANDAs are approved by the FDA, Mylan will induce infringement of the '693 Patent under 35 U.S.C. § 271(b). Janssen bears the burden of proving infringement by a preponderance of the evidence.

Janssen asserts that healthcare practitioners (*e.g.*, medical doctors) following Mylan's proposed ANDA labels will directly infringe the Asserted Claims, and that Mylan induces infringement because its ANDA labels will instruct healthcare practitioners to infringe the Asserted Claims.

Mylan disputes that there is direct infringement—a required showing for induced infringement—because, it asserts, infringement is "divided" between healthcare practitioners and patients. Mylan also disputes that there is induced infringement because, it asserts, it lacks specific intent. Mylan disputes that its proposed prescribing information encourages, recommends, or promotes infringement of the claimed method.

[2] This was Janssen's proposed POSA definition and Mylan does not object to that definition being adopted. Mylan proposed the following definition for the POSA: A POSA would have had (1) several years' experience in designing and formulating drug delivery systems including parenteral systems based on analyzing pharmacokinetic data such as blood serum or drug plasma levels and clearance rates and familiarity with depot formulations; (2) an advanced degree (Ph.D. and/or M.S.) in pharmaceutical sciences and/or pharmaceutics or a related degree; and (3) experience with the formulation of therapeutic agents, their dosing, and the literature concerning drug developmental study and design. Such a person would have understood that the process requires a multidisciplinary approach, and would have drawn upon not only his or her own skills, but also could have taken advantage of certain specialized skills of others to solve any given problem.

The parties set forth below, as to each infringement question, the key cases that they believe will assist the Court in preparing for trial:

> *Direct infringement under § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity. Is there direct infringement of the Asserted Claims?*

Janssen's Key Cases[3]	Mylan's Key Cases
• Method steps are actions that must be "carried out" for infringement to occur. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014). • Claims "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005 (en banc). • In interpreting the meaning of a claim, "[f]irst [the court] looks to words of the claims themselves." *Vitrionics Corp. v. Conceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). • "Method claim preambles often recite the [conditions] in which the claimed method is practiced." *Microprocessor Enhancement Corp. v. Tex. Instruments, Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008). • By contrast, the "the body of a method claim [consists of] method steps, which should usually be verbal (gerundial) phrase[s], introduced by a gerund or verbal non (the '-ing' form of a verb)." *AMAG Pharms., Inc. v. Sandoz, Inc.*, No. 16-cv-1508, 2017 WL 3076974, at *25 (D.N.J. July 19, 2017). • Thus, in a method-of-treatment claim, limitations defining the characteristics of a patient population that occurred before a medicine is administered (*e.g.*, having "been	**Infringement Generally** • A patent infringement analysis involves two steps: construing the claims and then the application of the construed claim to the accused process or product. *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). • It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." ***MicroStrategy Inv. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1351 (Fed. Cir. 2015).** • "Ordinary meaning is not something that is determined in a vacuum . . . . To the contrary, a word describing patented technology takes its definition from the context in which it was used by the inventor**." *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1320 (Fed. Cir. 2016)** (quotations and citations omitted). • "The only meaning that matters in claim construction is the meaning in the context of the patent." *Id*. at 1321 (quotations and citations omitted). • ***Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332 (Fed. Cir. 2003)** (Claim 5 "is an example of the claim drafter choos[ing] to use both the preamble and the body to define the

[3] Both sides agree that the portion of the preamble of claim 5 that states "wherein said patient had been last administered a PP3M injection 4 to 9 months ago" (693 Patent col. 21:13-14) is a *limitation*, or *requirement*, of the claim. The parties disagree as to whether this limitation constitutes a *step* in the claimed method. A preamble that is a limitation of the claim is not necessarily a step of the claims. *See Orexigen Therapeutics, Inc. v. Actavis Lab'ys FL, Inc.*, 282 F. Supp. 3d 793, 811-12 (D. Del. 2017), *aff'd in part, rev'd in part on other grounds sub nom. Nalproprion Pharms., Inc. v. Actavis Lab'ys FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019).

diagnosed") are not claim steps. *See Orexigen Therapeutics, Inc. v. Actavis Lab'ys FL, Inc.*, 282 F. Supp. 3d 793, 811-12 (D. Del. 2017), *aff'd in part, rev'd in part on other grounds sub nom. Nalproprion Pharms., Inc. v. Actavis Lab'ys FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019). • Since limitations defining characteristics of a patient population that occurred before administration are not steps of a method-of-treatment claim, infringement of such claims is not divided between healthcare professionals and patients. *See Orexigen*, 282 F. Supp. 3d at 811-12 (D. Del. 2017).[4]	subject matter of the claimed invention." (internal citations omitted)). • ***Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)** ("intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language"); *see id*. ("[T]he record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims."). • ***Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381** ("[W]here, as here, a patentee relies on language found in the preamble to successfully" overcome an invalidity challenge "it cannot later assert that the preamble term has no patentable weight for purposes of showing infringement.") • ***Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995)** ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."). **Direct Infringement**[5] • Direct infringement requires that a single party's activities meet all the limitations as claimed, in other words, to infringe a claim comprising a series of steps, "a person must have practiced all steps" of the claim. ***Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009).**

[4] Janssen's position is, and has always been, that the steps of the claimed method cover the administration of doses, not the missing of doses, and that therefore there is no divided infringement issue in this case. Furthermore, as explained in Janssen's sole Motion *in Limine* (Dkt. No. 81-1), the divided infringement issue, and Mylan's proposed construction of the claim to include missing a dose as a step of the method, were not properly disclosed in discovery. If Mylan is permitted to assert a new non-infringement argument and claim construction, Janssen reserves the right to respond to it depending on how the Court construes the claims and how the theory is articulated at trial.

[5] Further explanation of the cases and application to the facts of this case, including regarding claim construction, are included in Mylan's Brief in Support of its Motion *in Limine* No. 1 (Dkt. No. 82) and Mylan's Brief in Opposition to Plaintiffs' Motion *in Limine* (Dkt. No. 91). Further, Mylan disagrees with Janssen's characterization of facts as law, as the intrinsic record here makes clear the preamble includes a claim step attributable to patient action, unlike in *Orexigen Therapeutics, Inc. v. Actavis Lab'ys FL, Inc.*, 282 F. Supp. 3d. 793 (D. Del. 2017) *aff'd in part, rev'd in part on other grounds sub nom. Nalproprion Pharms., Inc. v. Actavis Lab'ys FL, Inc*., 934 F.3d 1344 (Fed. Cir. 2019).

	• "Where, as here, no single actor performs all steps of a method claim, direct infringement only occurs if 'the acts of one are attributable to the other such that a single entity is responsible for the infringement.'" ***Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017)** (quoting ***Akamai Technologies, Inc. v. Limelight Networks, Inc.* (*Akamai V*), 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) (per curiam), *cert. denied*, 578 U.S. 922, 136 S.Ct. 1661 (2016))**. • "Where more than one actor is involved in practicing the steps, a court must determine whether the acts of one are attributable to the other such that a single entity is responsible for the infringement. We will hold an entity responsible for others' performance of method steps in two sets of circumstances: (1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise." ***Akamai Techs., Inc. v. Limelight Networks, Inc.* (*Akamai V*), 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) (per curiam), *cert. denied*, 578 U.S. 922, 136 S.Ct. 1661 (2016)).**[6] • Directing or controlling others' performance includes circumstances in which an actor: (1) "*conditions* participation in an activity or receipt of a benefit" upon others' performance of one or more steps of a patented method, and (2) "*establishes the manner or timing* of that performance." *See Akamai V*, 797 F.3d at 1023 (emphases added). • In the context of prescription drugs, a patient's action is not "attributable to a prescribing physician solely because they have a physician-patient relationship." ***Eli Lilly & Co.*, 845 F.3d at 1368.**

[6] Plaintiffs have not put forth any theory of a "joint enterprise" or one entity "directing or controlling" the other as between healthcare professionals and patients regarding direct infringement. As such, the sole question for the Court at trial is whether there are multiple actors required for direct infringement or not and the parties do not separately provide case law regarding "joint enterprises" or one entity "directing or controlling" the other in the context of direct infringement.

Separate from the direct infringement inquiry, does Mylan possess the specific intent to induce infringement?

Janssen's Key Cases	Mylan's Key Cases
• Induced infringement requires a defendant to "possess specific intent to encourage another's infringement." *Vanda Pharms., Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1128 (Fed. Cir. 2018). • In an ANDA case, "[w]hen proof of specific intent depends on the label accompanying the marketing of a drug inducing infringement by physicians, the label must encourage, recommend, or promote infringement. The contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement." *Vanda* 887 F.3d at 1129 (citations and internal quotation marks omitted). • "Evidence that the product labeling that Defendants seek would inevitably lead some physicians to infringe establishes the requisite intent for inducement." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017). • Because 35 U.S.C. § 271(b) "on inducement, does not contain the 'substantial noninfringing use' restriction of section 271(c), on contributory infringement . . . . a person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses." *Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017).	• In order to prevail on a theory of induced infringement, "a plaintiff must prove (1) direct infringement and (2) 'that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement.'" ***Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018)** (citation omitted)). • The Federal Circuit has held that "the intent requirement for inducement requires more than just intent to cause the acts that produce direct infringement." ***DSU Med. Corp. v. JMS Co. Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).** • "The mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement." ***Eli Lilly & Co.*, 845 F.3d at 1368 (quoting *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)).** • When a product has substantial noninfringing uses, "intent to induce infringement cannot be inferred even [if the defendant] has actual knowledge that some users of its product may be infringing the patent." ***HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019)**; *see id*. (no inducement where "the label merely provided guidance to patients about what to do *if the patient desired* to" act according to the claimed steps (emphasis added)). • "[A] high prevalence of non-infringing uses . . . especially in an ANDA context, [] is relevant to the inquiry." ***Genentech, Inc. v. Sandoz, Inc.*, No. 19-cv-0078-RGA, 2022 WL 842957, at *9 (D. Del. Mar. 22, 2022)**; *see also id.* (Even though § 271(b) does not

	include the specific language regarding substantial noninfringing uses as § 271(c) does, the Federal Circuit in "*Vanda* did not go so far as to say the presence of substantial noninfringing uses is irrelevant to the inducement inquiry altogether.")

B. Validity

i. Obviousness (35 U.S.C. § 103)

Mylan asserts that the Asserted Claims are invalid as obvious under 35 U.S.C. § 103 over two combinations of references. Janssen disputes that the claims would have been obvious. Janssen also asserts that real-word evidence (*i.e.*, "objective indicia") supports the nonobviousness of the claims. Mylan disputes that such evidence supports the nonobviousness of the claims.

Mylan bears the burden of proving obviousness by clear and convincing evidence.

A patent claim is invalid as obvious if "the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Here, as mentioned above, the effective filing date is either April 7, 2015 or May 15, 2015, and, for purposes of obviousness, that difference will not affect the validity outcome.

Obviousness is a question of law based on underlying factual findings, known as the *Graham* factors: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective considerations of nonobviousness.

The key inquiries are: (a) would a person of ordinary skill have had a reason to combine the teaching of the prior art references to achieve the claimed invention; and (b) would the person of ordinary skill in the art have had a reasonable expectation of success in doing so.

The parties set forth below the key cases that they believe will assist the Court in preparing for trial on these questions:

> *Would a person of ordinary skill have had a reason to combine the teaching of the prior art references to achieve the claimed invention?*

Janssen's Key Cases	**Mylan's Key Cases**
• An "invention is not obvious simply because all of the claimed limitations were known in the prior art at the time of the invention." *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, 918 F.3d 928, 934-35 (Fed. Cir. 2019). • In other words, "[t]he determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claims. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008). • Thus, a "party seeking to invalidate a patent based on obviousness must demonstrate by clear and convincing evidence that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068-69 (Fed. Cir. 2012) (internal quotation marks omitted). • Mere recognition of a need "does not render the solution obvious" where "[t]here is no suggestion that the specified elements should be selected and combined" in the manner claimed. *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1273-74 (Fed. Cir. 2018). • Obviousness can be precluded where the prior art "teaches away" from the claimed invention—*i.e.*, if a POSA would be "discouraged" or "led in a direction	• "[T]he results of ordinary innovation are not the subject of exclusive rights under the patent laws." ***KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 427 (2007)**. • The person of ordinary skill in the art is a legal construct—a hypothetical person who is presumed to know all of the relevant prior art. *See* ***In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1576 (Fed. Cir. 1984)** (describing the POSA as "the inventor working in his shop with the prior art references—which he is presumed to know—hanging on the walls around him."). • The scope of the prior art includes art that is "reasonably pertinent to the particular problem with which the inventor was involved." *In re GPAC Inc.*, 57 F.3d at 1577. • "A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect." ***EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).** • Additionally, prior art references may be combined with the knowledge and/or experience of a POSA to "fill in the gap when limitations of the claimed invention are not specifically found in the prior art." ***Belden Techs., Inc. v. Superior Essex Commc'ns LP*, 802 F. Supp. 2d 555, 563 (D. Del. 2011); *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362-63**

divergent" from the clamed invention. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015).	**(Fed. Cir. 2013)** ("[T]he knowledge of such an artisan is part of the store of public knowledge that must be consulted when considering whether a claimed invention would have been obvious."). • "For obviousness, a single reference need not disclose every element of the claimed invention." *See, e.g.*, ***Hospira, Inc. v. Amneal Pharm., LLC*, 285 F. Supp. 3d 776, 783 (D. Del. 2018).** • "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." ***KSR*, 550 U.S. at 416; *see also* Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 FR 57526-01, 2007 WL 2936397 (F.R.)** (one rationale for obviousness includes "[u]se of known technique to improve similar devices (methods, or products) in the same way")

Would the person of ordinary skill in the art have had a reasonable expectation of success in doing so?

Janssen's Key Cases	**Mylan's Key Cases**
• "An obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art." *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1362-63 (Fed. Cir. 2009) (collecting cases). • "[T]o have a reasonable expectation of success, one must be motivated to do more than merely vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *Grünenthal GmbH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1345 (Fed. Cir. 2019).	• Obviousness does not require absolute predictability of success rather, "[a]ll that is required is a reasonable expectation of success" in making the invention via the combination. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (citation omitted). • "[T]here is no requirement that a teaching in the prior art be scientifically tested or even guarantee success before providing a reason to combine. Rather, it is sufficient that one of ordinary skill in the art would perceive from the prior art a reasonable likelihood of success." ***Duramed Pharm., Inc. v. Watson Labs., Inc.*, 413 Fed. Appx. 289, 294 (Fed. Cir. 2011).** • "A reference does not teach away . . . if it merely expresses a general preference for an

• "[E]vidence showing unpredictability in the art"—such as exists in chemistry, biology, and medicine—tends to show that a POSA would not have a reasonable expectation of success. *Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. De C.V.*, 865 F.3d 1348, 1354-56 (Fed. Cir. 2017) ("Unpredictability of results equates more with nonobviousness rather than obviousness . . . ."); *see also OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019); *Novartis Pharm. Corp. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051, 1061-62 (Fed. Cir. 2019).	alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed." ***Galderma Labs., L.P. v. Tolmar Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013); *see, e.g.*, *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005)** ("[District court erred] because a prior art reference that does not specifically refer to one element of a combination does not, per se, teach away. If it did, only reference that anticipate could be used to support an obviousness analysis [but that is not the law].").

Janssen bears the burden of producing evidence of objective indicia of nonobviousness (sometimes referred to as "secondary considerations"), but the ultimate burden of proving obviousness at all times remains with Mylan. Objective indicia of nonobviousness could include, among others, commercial success, industry praise, long-felt need, and copying by others. To be given weight in the obviousness analysis, such objective indicia evidence must have a nexus with the claimed invention.

The parties set forth below the key cases that they believe will assist the Court in preparing for trial on the questions of objective indicia and nexus:

Janssen's Key Cases	**Mylan's Key Cases**
• The Federal Circuit "has emphasized that consideration of the objective indicia is ***part of*** the whole obviousness analysis, not just an afterthought." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1357-58 (Fed. Cir. 2013). • "[O]pinions of this court should not be read to require a burden-shifting framework in derogation of [the] directive that objective evidence be considered before making in obviousness determination. *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1079; *accord Apple Inc. v. Samsung Elecs.*	• "[T]he presumption of validity does not relieve the patentee of any responsibility to set forth evidence in opposition to a challenger's prima facie case which, if left unrebutted, would be sufficient to establish obviousness." ***Novo Nordisk v. Caraco Pharm. Labs. Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013).** • Secondary considerations will not overcome a strong showing that the claimed invention was prima facie obvious. ***Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007)** ("[G]iven the strength

Co., Ltd., 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (citing *In re Cyclobenzaprine Hydrochloride*). • "Objective indicia can be the most probative evidence of nonobviousness in the record, and enables the court to avert the trap of hindsight." *Leo Pharm.*, 726 F.3d at 1358. • "Questions of nexus are highly fact-dependent and, as such are not resolvable by appellate-created categorial rules and hierarchies as to the relative weight or significance of proffered evidence." *WBIP, Inc. v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). • "A patentee may establish nexus absent the presumption by showing the objective indicia are the direct result of the unique characteristics of the claimed invention . . . ." *Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1277 (Fed. Cir. 2021) (internal quotation marks omitted). • "It is not necessary . . . that the patented invention be solely responsible for the [objective indicia], in order for this factor to be given weight appropriate to the evidence, along with other pertinent factors." *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991).	of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the claim] would have been obvious."). **Nexus** • Evidence concerning secondary considerations is not relevant to a determination of non-obviousness if a nexus between the claimed invention and the secondary consideration is lacking. ***Bosch Auto. Serv. Sols., LLC v. Matal*, 878 F.3d 1027, 1036 (Fed. Cir. 2017); See *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)** (party asserting secondary considerations "must submit some factual evidence that demonstrates the nexus"). • To weigh against a finding of obviousness, "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." ***Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008)**. • A nexus is only presumed "when the patentee shows that the asserted objective evidence is tied to a specific product and that product embodies the claimed features, and is coextensive with them." ***Quanergy Sys. Inc. v. Velodyne Lidar USA, Inc.*, 24 F.4th 1406, 1417-18 (Fed. Cir. 2022) (quoting *Fox Factory, Inc., v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019)** (internal quotations omitted)). "The coextensive requirement . . . requires the patentee to demonstrate that 'the product is essentially the claimed invention." *Id.* "A product is 'essentially the claimed invention' when, for example, 'the unclaimed features amount to nothing more than additional insignificant features.'" ***Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1276-77 (Fed. Cir. 2021)** (quoting *Demaco Corp. v. F. Von LAangsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1998)). **Long-felt But Unmet Need** • "Evidence of a long-felt need is only probative of nonobviousness . . . when both a

	demand existed for the patented invention, and others tried but failed to satisfy that demand." ***In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1083 (Fed. Cir. 2012).** • "Evidence of the long-felt need factor must squarely address the need satisfied by the asserted claims themselves." ***AstraZeneca LP v. Breath Ltd.*, 88 F. Supp. 3d 326, 387 (D.N.J. 2015), *aff'd*, 603 F. App'x 999 (Fed. Cir. 2015).** • "[T]he patentee must point to an articulated and identified problem and evidence of efforts to solve the problem that were, before the invention, unsuccessful." ***Apple Inc. v. Samsung Elecs. Co.*, 816 F.3d 788, 804-05 (Fed. Cir. 2016), *vacated in part on other grounds on reh'g en banc*, 839 F.3d 1034 (Fed. Cir. 2016).** **Commercial Success** • "Commercial success" is a legal construct that is premised on the idea that if a product is economically successful due to the novel and claimed features of the patent invention, it may provide objective evidence of nonobviousness of those claims. ***See, e.g., Merck & Co. Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376-77 (Fed. Cir. 2005).** But, "commercial success without invention will not make patentability." ***Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 153 (1950).** • "Evidence of commercial success . . . is only significant if there is nexus between the claimed invention and the commercial success." ***Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013).** **Failure of Others** • Unsuccessful attempts done before the publication of the asserted invalidating prior art generally have little relevance. ***See, e.g., Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 36 (1966)** ("unsuccessful attempts to reach a solution to the problems confronting [the inventor] made before that

	time [the invalidating prior art was published] became wholly irrelevant"). **Copying** • "[E]vidence of copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval." ***Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc*., 713 F.3d 1369, 1377 (Fed. Cir. 2013)**; *Galderma*, 737 F.3d at 740 ("The mere fact that generic pharmaceutical companies seek approval to market a generic version of a drug . . . does not support a finding of non-obviousness."); ***Allergan, Inc. v. Watson Labs., Inc.-Fla.*, 869 F. Supp. 2d 456, 485 (D. Del. 2012)** ("[A]s several courts have recognized, demonstration that a defendant has copied a patented invention is not compelling evidence of non-obviousness in the Hatch–Waxman context due to the unique nature of the ANDA process.").

ii. Written Description (35 U.S.C. § 112(a))

Mylan asserts that the Asserted Claims are invalid for failure to meet the written description requirement of 35 U.S.C. § 112. Janssen disputes that the claims lack sufficient written description. Mylan bears the burden of proving lack of written description by clear and convincing evidence.

To satisfy the written description requirement of 35 U.S.C. § 112, the description must clearly allow a POSA to recognize that the inventor invented what is claimed. In other words, the test for sufficiency is whether the disclosure reasonably conveys to a POSA that the inventors had possession of the subject matter of the Asserted Claims as of the effective filing date.

The parties set forth below the key cases that they believe will assist the Court in preparing for trial on the question of written description:

Janssen's Key Cases	**Mylan's Key Cases**

• "The hallmark of written description is disclosure. The standard for satisfying the written description requirement is whether the disclosure allows one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Alcon Research Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1190-91 (Fed. Cir. 2014). • "[W]ritten description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue." *Alcon*, 745 F.3d at 1191. • "[A] patentee may rely on information that is well-known in the art for purposes of meeting the written description requirement, because the specification is viewed from the perspective of one of skill in the relevant art." *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1359 (Fed. Cir. 2019).	• Whether a patent satisfies the written description requirement is a question of fact. *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1376 (Fed. Cir. 2019). • "[T]he hallmark of written description is disclosure," and "the test requires an objective inquiry into the four corners of the specification" to determine whether it "show[s] that the inventor actually invented the invention claimed." ***Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).** • The written description requirement is satisfied only if the inventor "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate[s] that by disclosure in the specification of the patent." ***Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011)** (internal quotations omitted).

iii. Enablement (35 U.S.C. § 112(a))

Mylan asserts that the Asserted Claims are invalid for failure to meet the enablement requirement of 35 U.S.C. § 112. Janssen disputes that the claims lack enablement. Mylan bears the burden of proving lack of enablement by clear and convincing evidence.

A patent claim satisfies the enablement requirement of 35 U.S.C. § 112 if a POSA, having read the specification of the patent-in-suit, would be able to make and use the full scope of the claimed invention without "undue experimentation."

The parties set forth below the key cases that they believe will assist the Court in preparing for trial on the question of enablement:

Janssen's Key Cases	Mylan's Key Cases
• "Whether undue experimentation is required is not a single, simple factual determination,	• ***ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010)** ("To be

but rather is a conclusion reached by weighing many factual considerations [*i.e.*, the *Wands* factors]." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (internal quotation marks omitted); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). • "The question of undue experimentation is a matter of degree . . . . [E]xtensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques." *Cephalon*, 707 F.3d at 1338. • "A patent does not need to guarantee that the invention works for a claim to be enabled. And efficacy data are generally not required in a patent application. Only a sufficient description enabling a person of ordinary skill in the art to carry out an invention is needed." *Allergan Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) (citations and internal quotation marks omitted). • Rejecting an argument akin to Mylan's here—that "if the asserted claims are nonobvious, they cannot possibly be enabled"—the Federal Circuit has explained: "The obviousness inquiry turns on what the prior art would have taught a [POSA] and whether the claimed invention would have been obvious in view of the ***prior art***. . . . In contrast, the enablement inquiry turns on whether the skilled artisan, after reading the ***specification***, would be able to make and use the claimed invention without undue experimentation, based on the ordinary skill in the art." *Allergan*, 796 F.3d at 1310.	enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." (internal quotations and citations omitted)); *see also*, ***Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).** • ***MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012)** ("[Enablement] prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage."). • "[T]he question of undue experimentation is a matter of degree." ***PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996)**. • In ***In re Wands***, the Federal Circuit set forth a set of factors in determining undue experimentation. **858 F.2d 731, 737 (Fed. Cir. 1988).** • A court need not consider every one of the *Wands* factors in its analysis, rather, a court is only required to consider those factors relevant to the facts of the case. *See, e.g.*, ***Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999)** ("[A]ll of the factors need not be reviewed when determining whether a disclosure is enabling.").

iv. Indefiniteness (35 U.S.C. § 112(b))

Mylan asserts that the Asserted Claims are invalid for indefiniteness 35 U.S.C. § 112(b), specifically with respect to the terms "PP3M" and "PP1M." Janssen disputes that the claims are indefinite. Mylan bears the burden of proving indefiniteness by clear and convincing evidence.

A patent claim satisfies the definiteness requirement if the specification of the patent-in-suit informs, with reasonable certainty, a POSA about the scope of the invention.

The parties set forth below the key cases that they believe will assist the Court in preparing for trial on the question of indefiniteness:

Janssen's Key Cases	Mylan's Key Cases
• The Supreme Court announced the applicable standard for indefiniteness in 2014: "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). • "'Reasonable certainty' does not require 'absolute or mathematical precision.'" *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (quoting *Nautilus*). • "[A]n inventor need not explain every detail because a patent is read by those of skill in the art." *BASF*, 875 F.3d at 1366. • "[T]he written description is ***key***" to the question of indefiniteness, and "express definitions," "functional characteristics," "examples and metrics" (as well as "extrinsic evidence") all can provide a POSA with the "reasonable certainty" about the scope of the invention. *Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1360-62 (Fed. Cir. 2019).	• "Because claims delineate the patentee's right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent**." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008)** (citing *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996)); ***Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).** • Not only can individual claim terms be indefinite, but a claim that fails to interrelate essential claimed elements of the invention can also be indefinite**. *In re Venezia*, 530 F.2d 956, 959-960 (C.C.P.A. 1976); *In re Collier*, 397 F.2d 1003, 1005 (C.C.P.A. 1968).** It is not enough that each claim term be clearly understood by the POSA, but definiteness also requires a clear description of how those claims terms are combined together to arrive at the claimed invention. *Id.*

v. Patent Eligibility (35 U.S.C. § 101)

Mylan asserts that the Asserted Claims are invalid for failure to meet the patent eligibility requirement of 35 U.S.C. § 101. Janssen disputes that the claims are patent ineligible. Mylan bears the burden of proving that the claims are patent ineligible by clear and convincing evidence.

A patent claim fails to meet the patent eligibility requirement of 35 U.S.C. § 101 if the claimed invention is solely directed to patent ineligible subject matter (*i.e.*, laws of nature, natural phenomena, or abstract ideas).

The parties set forth below the key cases that they believe will assist the Court in preparing for trial on the question of patent eligibility:

Janssen's Key Cases	**Mylan's Key Cases**
• The Supreme Court's two-step test for assessing patent eligibility is set forth *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014), and *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012). • "While the ultimate determination of eligibility under § 101 is a question of law, there can be subsidiary fact questions which must be resolved en route to the ultimate legal determination." *Aatrix Software v. Green Shades Software*, 882 F.3d 1121, 1128 (Fed. Cir. 2018). • Under the Supreme Court's *Alice*/*Mayo* test, claims that "recite steps of carrying out a dosage regimen based on the results of genetic testing" are not patent ineligible. *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1134-37 (Fed. Cir. 2018).	• "The ultimate question of patent eligibility under § 101 is an issue of law." *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Pat. Litig.*, 774 F.3d 755, 759 (Fed. Cir. 2014). • The Supreme Court has carved out the following exceptions to patent eligible subject matter: laws of nature, natural phenomena, and abstract ideas**. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015)** (citing ***Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014))**. • The Supreme Court has provide a two part test to determine whether a claim is patent eligible and, thus, not solely directed to a law of nature, natural phenomenon, or abstract idea. The first step is to determine whether the claim is directed to a patent-ineligible concept." *Ariosa*, 788 F.3d at 1375-6. "If the answer is yes, then [the court] next consider[s] the elements of each claim both individually and 'as an ordered combination' to determine whether additional elements 'transform the nature of the claim' into a patent-eligible application." *Arisoa*, at 1375 (quoting *Mayo Collab. Servs. V. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1298 (2012)). This second step in the analysis involves the determination of whether the claim includes an "inventive concept" that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Id*. • "Laws of nature, natural phenomena, and abstract ideas are the basic tools of scientific

	and technological work. Monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it, thereby thwarting the primary object of the patent laws." ***Alice Corp. Pty. v. CLS Bank Int'l,* 573 U.S. 208, 216, 134 S. Ct. 2347, 2354 (2014)** (internal citations and quotations omitted).

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Respectfully submitted,

s/ Keith J. Miller
Keith J. Miller
Michael J. Gesualdo
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
(973) 690-5400

Barbara L. Mullin (admitted *pro hac vice*)
Aron R. Fischer (admitted *pro hac vice*)
Andrew D. Cohen (admitted *pro hac vice*)
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorneys for Plaintiffs Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LLC

s/ Arnold B. Calmann
Arnold B. Calmann
Jeffrey Soos
Katherine A. Escanlar
SAIBER LLC
One Gateway Center, 10th Floor
Newark, NJ 07102-5311
(973) 622-3333

Deepro R. Mukerjee (admitted *pro hac vice*)
Lance A. Soderstrom (admitted *pro hac vice*)
KATTEN MUCHIN ROSENMAN LLP
50 Rockefeller Plaza
New York, NY 10020-1605
(212) 940-8800

Attorneys for Defendant Mylan Laboratories Limited, Inc.